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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,026	11/27/2001	En-Chung Lin	Lee&Li 103	9623

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EXAMINER

SWITZER, JULIET CAROLINE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/995,026	LIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Juliet C. Switzer	1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 6-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of group I, claims 1-5 in the paper filed 4/28/03 is acknowledged. The traversal is on the ground(s) all three inventions are "sufficiently related that the Examiner can search all three groups of claims directed to the methods called for in the claims in a single search, since as the Examiner has indicated in her requirement for restriction that all of the methods called for in the claims are classified in class 435, subclass 6." This is not found persuasive because though the inventions are commonly classified, this classification is not an indication that the search of the invention would be coextensive in fact. The class 435, subclass 6 currently contains over sixteen thousand patents, and so, even a mere review of the classification is an extensive search. Furthermore, the search and consideration of the three different groups will involve separate analysis of the prior art, both patent and non-patent for references that deal with each of the particularly recited traits that are being detected using the claimed methods. Though the three inventions involve polymorphisms within the same promoter, each invention is directed towards a separate goal, that is to detect pigs with different traits, and each invention utilizes a different set of genotypes as indicators of the presence of the trait. The consideration of each separate invention requires separate consideration of data provided and of the teachings of the prior art. Therefore, the search and examination of the separate inventions poses a significant burden on the examiner. The requirement is still deemed proper and is therefore made FINAL.

***Claim Objections***

2. Claim 3 is objected to because of the following informalities: there is not subject/verb agreement between the singular “method” and the plural “comprise.” Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 are indefinite over the recitation of “thin backfat thickness” because this is an entirely relative term which is given no reference or definition in either the claims or the specification. The specification defines how to calculate backfat thickness, but the specification does not give any indication as to what values for backfat thickness are considered “thin” versus any other backfat descriptor. The claims would be clearer if they recited that the method is for detecting pigs with an increased likelihood of having thinner backfat than some standard of comparison, for example an empirical value or a different group of pigs.

Claims 1-5 are indefinite over the recitation “polymorphism characterized by nucleotide position...” because it is not clear what it means for a polymorphism to be characterized by a particular nucleotide position. It is not clear, for example, if this means that the position itself is polymorphic, that the polymorphism is somehow identified or related to the nucleotide position,

etc. It would be clearer to recite that the identifying step is one of identifying a nucleotide present at a particular nucleotide position.

Claims 1-5 are indefinite over the recitation "position 393 of the 5'-flanking region of porcine HSP70.2 gene" because the position of a nucleotide within a sequence is entirely dependent upon the first nucleotide in the sequence, but neither the claims nor the specification provide a reference from which to begin counting so as to arrive at position 393 with any clarity. Disclosures of 5' flanking regions of genes, especially, are not uniform throughout the art, so it is critical to know for the practice of this invention how to identify the particular polymorphic site of interest. The claims are indefinite because they do not set forth the identity of the polymorphic site with clarity. Each of claims 3, 4, and 5 are further indefinite over the additional recitation of polymorphisms characterized by positions that are not clearly defined with respect to the sequence the numeric position is embedded within.

Claim 5 is indefinite because it includes method limitations of assaying four polymorphic sites (393, 250, 44, and 232), yet it recites a final process step which has a genotype containing five positions. The method does not recite a process step of identifying a polymorphism at any position 345, thus it is unclear if this is a required step in the method and further, what the position 345 polymorphism is not defined.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has not provided adequate written description of methods for identifying the polymorphisms of the claimed invention. In particular, applicants have not provided written description for the location of the polymorphism within any particular sequence. The specification teaches that the "5'-flanking region of porcine *HSP70.2*" is the upstream sequence of the porcine *HSP70.2* gene which has a certain set of structural feature commonly found in 5' untranslated regions of genes and is 91% homogenous (homologous) to a sequence taught by Peelman *et al.* However, the sequence of the region itself is not disclosed in the specification, and thus, it is not known which nucleotides of which recitation of the *HSP70.2* 5' untranslated region applicant is referring to. The numbering of a particular nucleotide sequence is entirely dependent upon the length of the sequence, and can be effected, for example by amplification primers used to obtain a sequence, or how much of a 5' untranslated region is isolated. The specification does not provide any written description of the polymorphisms referred to therein as being characterized by nucleotide positions 44, 232, 250, 345, and 393 of the 5'-flanking region of the porcine *HSP70.2* gene, and thus lacking this critical information, the instant specification does not provide adequate written description for the practice of the claimed invention.

7. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for selecting Duroc pigs with an increased likelihood of having thinner backfat thickness wherein said method comprises identifying the nucleotide present at positions 44, 232, 250, 345, and 393 of the 5'-flanking region of the porcine HSP70.2 gene, wherein the presence of the genotype CCATT/CCATT indicates that the pig is more likely to have thinner backfat thickness than a pig with either of the genotypes CCATC/CCATC or CCATC/AAACC, does not reasonably provide enablement for methods for selecting pigs with thinner backfat thickness from any type of breed or methods which identify the nucleotide present at less than all five of the polymorphic sites, or methods which recite that the pigs with the CCATT/CCATT will have thinner backfat thickness than any pigs other than those with CCATC/CCATC or CCATC/AAACC genotypes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

#### **Breadth of the Claims and Nature of the Invention**

The rejected claims are drawn to a method for selecting pigs with "thin" backfat thickness and comprise steps of identifying a polymorphism present at one, two, three, four or five different polymorphic sites. The claims encompass such a selection method for any breed of pig, with the exception of claim 2 which recites that the pigs are one of three breeds.

The nature of the invention is that it can be used to select pigs more likely to have thinner backfat thickness than some of their peers, backfat thickness being a growth performance measure for pigs.

#### **Guidance in the Specification and Working Examples**

The specification the genotyping of 119 purebred Duroc pigs for five polymorphisms within the 5'-flanking region of the *HSP70.2* gene, and subsequent haplotype analysis to determine if there is any association between any particular haplotypes and the trait of backfat thickness. The specification teaches that haplotype analysis was used to "maximize the amount of information about the SNPs (p. 11, line 6)." The specification does not teach the results of any analysis for associations between any set of one, two, three, or four polymorphisms and backfat thickness. The specification only provides statistical analysis for the full haplotypes of five nucleotides.

Table 3 of the specification shows that pigs with the haplotype CCATT/CCATT have backfat thickness that is statistically the same as that of three other genotypes, and notably, as a genotype that is C/C for position 393. The haplotype CCATT/CCATT had a backfat thickness that was lower than two of the genotypes listed in Table 3. Table 4 of the specification shows that during winter, pigs with CCATT/CCATT genotype have a backfat thickness that is statistically the same as those with one other genotype, but that are lower than all other genotypes. Thus, weighing the data in the specification show that the CCATT/CCATT genotype is only definitively an indicator that a Duroc pig has an increased likelihood of thinner backfat thickness than only two genotypes in particular, the CCATC/CCATC or CCATC/AAACC genotypes.

The specification does not provide any working examples that exemplify using less than all five nucleotide positions as an indicator of thinner backfat thickness. The specification does not provide any examples which show that the CCATT/CCATT genotype is an indicator of thinner backfat thickness than all other possible genotypes, since the specification in fact shows



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that pigs with this genotype have statistically the same backfat thickness as at least three other genotypes.

### **State of the Prior Art and Unpredictability**

The prior art teaches an association of an SPI box transition within the *HSP70.2* gene and birth weight, and the results of carcass composition and meat quality traits were inconsistent in different populations (Maak *et al.* 1998. *Animal Genetics* 29 (Suppl. 1) 60-74). Further, Maak *et al.* (1999. *Arch. Tierz., Dummerstorf* 42(1999) Special Issue, 141-143) teach that results testing different groups of pigs varied when testing for associations between *HSP70.2* polymorphisms and pig quality traits. Thus, the prior art establishes that especially for this gene, it is highly unpredictable whether any observed association between a trait and a polymorphism within a particular population will be predictive for another population. Maak *et al.* (1999) were unable to observe any correlation between *HSP70.2* polymorphisms and pigs from a Berlin-Bonn resource population, including for back fat.

Furthermore, given an association between a particular haplotype and a trait, it is highly unpredictable which individual nucleotide within that haplotype will be informative for a trait, if any nucleotide at all will be powerful enough. For example, Ulbrecht *et al.* (*Am J Respir Crit Care Med* 2000, 161:469-474) were unable to detect any association between individual polymorphisms and bronchial hyperresponsiveness, but were able to detect an association between haplotypes using the individual polymorphisms (p. 471-472). Thus, with regard to the instantly claimed invention, it is highly unpredictable as to whether any smaller units of the haplotype would provide sufficiently powerful associations so as to be predictive of backfat thickness.

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**Conclusion**

Given the breadth of the claims, the limited nature of the working examples and guidance in the specification, and the unpredictability in the state of the art, it is concluded that undue experimentation would be required to practice the invention commensurate in scope claims.

***Conclusion***


8. No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

July 10, 2003

  
Juliet C Switzer  
Examiner  
Art Unit 1634

  
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